Professor Dr. med. Tino Schwarz

Klinikum Würzburg Mitte
Standort Juliusspital

List of Clinical Trials

Phase	Titel	Start	Funktion
Phase I/II	A Phase 1/2 randomized, observer-blinded, multi-country study to evaluate safety and immunogenicity of investigational adjuvanted human papillomavirus vaccine in females (16 to 26 years of age) (213749 (HPV9-AS04-001) **EudraCT number: 2022-000090-15**	2023	PI
Phase III	A Phase 3, observer-blind, randomized, placebo-controlled study to evaluate the non-inferiority of the immune response and safety of the RSVPreF3 OA investigational vaccine in adults 50-59 years of age, including adults at increased risk of respiratory syncytial virus lower respiratory tract disease, compared to older adults ≥60 years of age. (219238 (RSV OA=ADJ-018) **EudraCT nummer 2022-001981-36**	2022	PI
Phase III	A phase 3 randomised observer-blind placebo controlled, obserever-blinded, multi-country study to demonstrate the efficacy of a single dose of GSK`s RSVPreF3 OA investigational vaccine in adults aged 60 years and above (RSV OA=ADJ-006; GSK-212494) **EudraCT-Nummer 2020-000753-28**	2021	PI
Phase III	A phase 3 randomised open-label, multi-country study to evaluate the immunogenicity, safety and reactogenicity of a single dose of the RSVPreF3 OA investigational vaccine and different revaccination schedules in adults aged 60 years and above (RSV OA=ADJ-004; GSK-212496) **EudraCT-Nummer 2019-004680-51**	2021	PI
Phase II/III	A phase 1/2, multicenter, randomized, observer-blinded, active controlled clinical study to assess the safety and immunogenicity of the Tetanus, Diphtheria and accellular Pertussis Vaccine SIIPL Tdap in Comparison with Boostrix in Helthy Adults, Adolescents and Children (DE-3.01_ SII-Tdap /TADEUS / PAREXEL) **EudraCT-Nummer 2019-002706-46**	2020	PI
Phase I/II	A phase 1/2 randomised observer-blind placebo controlled study to evaluate the safety, reactogenicity and immunogenicity of different dose levels of GSK Biologicals' investigational unadjuvanted RSV maternal vaccine (GSK3888550A) compared to placebo when administered to healthy non-pregnant women aged 18-45 years. (RSV MAT-001 GSK-208068). **EudraCT-Nummer 2018-001340-62**	2019	PI
Phase IIb	A phase 2b, randomized, controlled, observer-blind, multi-center, non-inferiority immunogenicity and safety study of two formulations of GSK Biologicals' Meningococcal ACWY conjugate vaccine (GSK3536820A and Menveo) administered to healthy adults 18 to 40 years of age (MENACWY CONJ-032 (V59_71) GSK-205343). **EudraCT-Nummer 2017-003692-61**	2018	PI
Phase III	A Phase 3b, randomized, open-label, multicentre clinical trial to assess the immunogenicity and safety of Herpes Zoster vaccine co-administered with Prevenar13 in adjults aged 50 years and older. (Zoster-059 PRI GSK-204487). **EudraCT-Nummer 2017-001220-22**	2018	PI
Phase IV	A phase 4, open-label,randomized study to enrol healthy adult volunteers, naive to any previous meningococcal vaccination or meningococcal infection, aged 18-50 years, to be either vaccinated with Menveo or Bexsero and serve as donors of human serum to be used in the development, qualification,validation and maintenanance of immunological assays. (BIO MENB REC 2ND GEN-079 HBS GSK-207911) **EudraCT-Nummer 2017-002919-33**	2018	PI

Professor Dr. med. Tino Schwarz

Klinikum Würzburg Mitte
Standort Juliusspital

List of Clinical Trials

Phase II	A Phase 2, randomised, observer-blind, multi-centre study to assess to evaluate the safety, reactogenicity and immunogenicity of GSK Biologicals GSK3277511A investigational vaccine when administered intramuskularly according to two different vaccine schedules in adults aged 40 to 80 years old. (NTHI MCAT-008 GSK-207759). **EudraCT-Number 2017-002941-31**	2018	PI
Phase III	A phase 3, placebo-controlled, randomized, observer-blinded study to evaluate the efficacy, safety, and tolerability of a clostridium difficile vaccine in adults 50 years of age and older. (Clover Pfizer B5091007). **EudraCT-Nummer 2016-003866-14**	2017	PI
Phase II	A phase II, randomised, observer-blind, controlled, multi-country study to rank different formulations of GSK Biologicals`investigational RSV vaccine (GSK3003891A), based on immunogenicity, reactogenicity and safety, when administered to healthy women, aged 18-45 years. (RSV F-021 GSK-204812). **EudraCT-Nummer 2016-001135-12**	2017	PI
Phase IV	A phase IV, open-label, multicentre study to assess the long-term persistence of antibodies against hepatitis B and the immunogenicity and safety of a challenge doses of hepatitis B vaccine (Engerix-BTM Kinder SKF103860) in children aged 14-15 years, previously primed and boosted in the first two years of life with four doses of GSK Biologicals`DTPa-HBV-IPV/Hib (Infanrix TM hexa SB217744) vaccine. (DTPA-HBV-IPV-115 EMA-115 GSK-106794). **EudraCT-Nummer 2015-003391-74**	2016	PI
Phase IIIb	A phase IIIb, non-randomized, open-label, multi-country, multi-centric cross-vaccination study to evaluate the safety of GSK Biologicals´Herpes Zoster subunit (HZ/su) vaccine when administered intramuscularly on a two-dose schedule to subjects who previously received placebo in ZOSTER-006 and Zoster-022 studies.(Zoster-056 GSK-204486). **EudraCT-Nummer 2015-000965-30**	2016	PI
Phase IIIb	A phase IIIB, open, long term extension study to evaluate the persistence of immune responses and the safety of GSK Biologicals`Herpes Zoster subunit (HZ/su) vaccine 1437173A, at months 108 and 120 post-vaccination and assessment of re-vaccination with two additional doses administered at 10 years after the initial vaccination in study Zoster-003 in healthy subjects aged 60 years and older. (Zoster-060 (Ext 03) GSK-204926). **EudraCT-Nummer 2015-004400-30**	2016	LKP, PI
Phase IIIb	A phase IIIb, open-label, multi-country, long-term follow study (ZOE-LTFU) of studies 110390 and 113077 (Zoster-006/022) to assess the prophylactic efficacy, safety, and immunogenicity persistence of GSK Biologicals` Herpes Zoster subunit HZ/su) vaccine and assessment of 1 or additional doses on a 0, 2-month schedule in two subgroups of older adults. (Zoster-049 GSK-201190). **EudraCT-Nummer 2015-001778-17**	2016	PI
Phase III	**E**ffekt einer **c**oordinierten **H**ilfestellung für **T**umorpatienten durch repetitive Supportivangebote: **e**ine prospektive **r**andomisierte kontrollierte Studie (ECHTER-001) EudraCT-Nummer N/A	2016	Subinvestigator

List of Clinical Trials

Phase II	A phase II, randomised, observer-blind, controlled, multi-country study to assess the safety, reactogenicity and immunogenicity of a single intramuscular dose of different formulations of GSK Biologicals`investigational RSV vaccine (GSK3003891A), in healthy women aged 18 to 45 years. (RSV-020 GSK-201510). **EudraCT-Nummer 2014-002688-14**	2014	PI
Phase III	A phase 3, stratified, randomised, controlled, observer-blind, multicenter study to evaluate the safety, tolerability, and immunogenicity of two doses of aH5N1 when administered to adult and elderly subjects with and without underlying medical conditions. (NOVARTIS V87_25). **EudraCT-Nummer 2011-003603-37**	2014	PI
Phase III	A Phase III, double-blind, randomised, multicenter study to assess safety and immunigenicity of GlaxoSmithKline Biologicals`quadrivalent split virion influenza vaccine (GSK2321138A) manufactured with a new process, in adults aged 18 to to 49 and in children aged 6 months to 17 years. (FLU D-QIV-015 GSK-201251). **EudraCT-Nummer 2014-000955-10**	2014	PI
Phase III	A phase 3, randomised, active-controlled, observer-blinded trial to assess the safety and tolerability of a meningococcal seroproup B bivalent recombinant lipoprotein (rLP2086) vaccine given in healthy subjects aged 10 to 26 years. (Pfizer B1971014 (6108A1-3003)). **EudrCT-Nummer 2009-015198-11**	2013	PI
Phase III	A phase 3, randomized, active-controlled, observer-blinded trial to assess the lot consistency, safety, tolerability, and immunogenicity of a meningococcal serogroup B bivalent RLP2086 vaccine in healthy subjects aged >10 to >19 years. (Pfizer B1971009 (6108A1-3001)). **EudraCT-Nummer 2010-023873-20**	2013	PI
Phase III	A phase III, randomized, open-label, multicentre clinical trial to assess the immunogenicity and safety of GSK Biologicals' Herpes Zoster vaccine GSK1437173A when co-administered with GSK Biologicals' quadrivalent influenza vaccine FLU-D-QIV (GSK2321138A) versus separate administration of the two vaccines in adults aged 50 years and older. (Zoster-004 GSK-117036). **EudraCT-Nummer 2013-000372-15**	2013	LKP, PI
Phase III	A phase III, randomised, partally-blind, controlled, multi-centric, multi-country study to evaluate the immunogenicity, safety and reactogenicity of GSK Biologicals` MenACWY-TT conjugate vaccine co-adminsitered with Boostrix administered intramuscularly versus MenACWY-TT alone adminisierted intramuscularly, in healthy adolescents and young adults between 11 and 25 years. (MEN ACWY-TT-098 GSK-116705). **EudraCT-Nr. 2012-002737-11**	2013	PI, LKP
Phase III	A Phase IIIb open-label, randomised, multicentre primary immunization study to evaluate the immunogenicity and safety of GSK Biologicals´HPV-16/18 L1 VLP AS04 vaccine when adminsitered intramuscularly according to alternative 2-dose schedules in 9-14 year old healthy females compared to standard 3-dose schuedule for GKS Biologicals`HPV-16/18 L1 VLP AS04 vaccine in 15-25 year old healthy females. (HPV-070 GSK-114700). **EudraCT-Nummer 2011-000757-22**	2012	PI

Professor Dr. med. Tino Schwarz

Klinikum Würzburg Mitte
Standort Juliusspital

List of Clinical Trials

Phase IV	A phase IV, open-label, non-randomised, multicentre study to assess the immunigenicity and reactogenicity of a booster dose of GSKBiologicals`combined reduced-antigen-content diphtheria-tetanus, acellular pertussis and inactivated poliovirus vaccine (dTpa-IPV (Boostrix-Polio) when administered in healthy adults, 10 years after a booster vaccination in study 711866/003 (dTpa-IPV-003). (BOOSTRIX-IPV-012 GSK-113060). **EudraCT-Nummer 2009-012219-16**	2011	PI
Phase III	A Phase III Stratified, Randomized, Controlled, Observer-Blind, Multicenter Study to Evaluate the Safety, Tolerability, and Immunogenicity of Two Doses of aH5N1 when Administered to Adult and elderly subjects with and without underlying medical conditions. (NOVARTIS V87_26). **EudraCT-Nr. 2011-003573-28**	2011	PI
Phase III	A phase III, randomized, observer-blind, placebo-controlled, multicentre, clinical vaccination trial to assess the prophylactic efficacy, safety, and immunogenicity of GSK Biologicals`gE/AS01B vaccine when adminsitered intramuscularly on a 0,2-month schedule in adults aged 50 years and older. (Zoster-006 GSK-110309). **EudraCT-Nummer 2008-000367-42**	2010	PI
Phase III	A phase III, randomized, observer-blind, placebo-controlled, multicentre, clinical vaccination trial to assess the prophylactic efficacy, safety, and immunogenicity of GSK Biologicals`gE/AS01B vaccine when adminsitered intramuscularly on a 0,2-month schedule in adults aged 70 years and older. (Zoster-022 GSK-113077). **EudraCT-Nummer 2009-015791-94**	2010	PI
Phase II	An open, phase II long term extension study to evaluate the immune responses to and safety of GSK Biologicals' candidate herpes zoster vaccine, (gE/AS01B), at Months 48, 60 and 72 post-vaccination in healthy subjects aged 60 years of age and older. (Zoster-024 (ext-013) GSK-114825). … **EudaCT-Nr 2010-022248-19**	2010	PI
Phase III	A phase III, observer-blind, randomized, study in adults aged between 18 and 60 years to assess the immunological equivalence of the Quebec-manufactured A/California/7/2009 (H1N1)v-like antigen adjuvanted with AS03A as compared to the Dresden-manufactured A/California/7/2009 (H1N1)v-like antigen adjuvanted with AS03. (FLU D-PAN-017 GSK-113535). **EudraCT-Nr. 2009-014419-11**	2009	PI
Phase II	A phase II, randomized, multicentre, observer-blind study to compare and characterize the immunoginicity and safety parameters induced by various GSK Biologicals' Adjuvant Systems in combination with the Hepatitis B surface antigen (HBsAg), according to a 0, 1 month schedule with a booster at Month 12, in healthy, Hepatitis B virus (HBV) naïve, adults. (EARLY-CLINRES-002 GSK-112115). **EudraCT-Nr. 2008-004455-29**	2009	PI
Phase III	A randomized, single-blind, dose-ranging, study to evaluate immunogenicity, safety and tolerability of different formulations of adjuvanted egg-derived, inactivated novel swine origin A/H1N1 monovalent subunit influenza virus vaccine in healthy subjects 18 or more years of age. (NOVARTIS V111_02). **EudraCT-Nr. 2009-013671-21**	2009	PI
Phase III	A randomized, single-blind, dose-ranging, study to evaluate immunogenicity, safety and tolerability of different formulations of adjuvanted egg-derived, inactivated novel swine origin A/H1N1 monovalent subunit influenza virus vaccine in healthy subjects from 6 month to 17 years of age. (NOVARTIS-V111_03). **EudraCT-2009-013672-45**	2009	PI

Professor Dr. med. Tino Schwarz

Klinikum Würzburg Mitte
Standort Juliusspital

List of Clinical Trials

Phase III	A randomized, single-blind, dose-ranging, study to evaluate immunogenicity, safety and tolerability of different formulations of adjuvanted and non adjuvanted cell-derived, inactivated novel swine origin A/H1N1 monovalent subunit influenza virus vaccine in healthy subjects 18 or more years of age. (NOVARTIS V110_03). **EudraCT-Nr. 2009-013639-39**	2009	PI
Phase III	A randomized, single-blind, dose-ranging, study to evaluate immunogenicity, safety and tolerability of different formulations of adjuvanted and non adjuvanted cell-derived, inactivated novel swine origin A/H1N1 monovalent subunit influenza virus vaccine in healthy subjects from 6 months to 17 years of age. (NOVARTIS V110_04). **EuraCT-2009-013672-45**	2009	PI
Phase IIIb	A phase IIIb, open, multi centre gynaecological extension study for follow-up of a subset of 580299/008 study subjects who were either cervical cytology negative and oncogenic HPV positive or pregnant at their final 580299/008 study visit (Visit 10 at Month 48). (HPV-052 ext 008 GSK-112024). **EudraCT-Nummer 2008-008124-33**	2009	PI
Phase IV	Unverblindete Langzeit-Nachbeobachtung der Immunogenität und Sicherheit des HPV-16/18-VLP/AS04-Impfstoffs von GlaxoSmithKline Biologicals bei gesunden Probandinnen bis zu 10 Jahre lang nach der Verabreichung der ersten Impfdosis im Rahmen der Studie HPV-013. (HPV-025 GSK-111375). **EudraCT-Nr. 2008-000369-44**	2009	PI
Phase III	A long-term, open, age-stratified follow-up of the imnunogenicity and safety of GlaxoSmithline Biologicals`HPV-16/18 L1/AS04 vaccine in healthy female subjects vaccinated in study HPV-014. (HPV-060 GSK-112772). **EudraCT-Nummer 2009-011357-41**	2009	PI
Phase III	Randomisierte, Beobachter-verblindete, Verum-kontrollierte Phase III Studie zum Nachweis der überlegenen Wirksamkeit des adjuvantierten Influenza-Kandidatimpfstoffs (GSK2186877A) von GSK Biologicals nach intramuskulärer Verabreichung an ältere Probanden ab 65 Jahren im Vergleich zu Fluarix. (FLU-NG-006 PRI GSK-106372). **EudraCT-Nummer 2008-000872-25**	2008	PI
Phase II	A phase II, controlled, randomized, multicentre, single blind study to evaluate the immunogenicity, safety and reactogenicity of the low dose influenza vaccine with various doses of the AS03 adjuvant compared to Fluarix TM (GlaxoSmithKlineBiologicals) administered intramuscularly in subjects aged 18-64 years. (FLU-LD-012 GSK-110794). **EudraCT-Nummer 2007-003776-18**	2008	PI
Phase Ib	A phase Ib, multi-center, randomized , observer-blind, proof of concept, dose- and formulation-ranging study to evaluate safety, tolerability, and immunogenicity of one dose of trivalent inactivated influenza vaccine in diffefrnt presentations (intramuscular and intradermal delivery), dosages (regular or highher A/h3N2 content) and adjuveantation (MF59 and/or IC31) administered to healthy elderly aged >65 years. (NOVARTIS V104P3). **EudraCT Nummer 2008-002625-36**	2008	LKP, PI

Professor Dr. med. Tino Schwarz

Klinikum Würzburg Mitte
Standort Juliusspital

List of Clinical Trials

Phase III	A phase 3, open-label single-arm trial evaluating the safety, tolerability, and reactogenicity of a 13-valent pneumococcal conjugate vaccine in ambulatory elderly adults aged 68 years and older who received 1 or more doses of 23-valent pneumococcal polysaccharide vaccine at least 3 years before study enrollment. (Wyeth 6115A1-3000). **EudraCT Number: 2007-002683-10**	2008	LKP, PI
Phase IIIb	Randomisierte, unverblindete, multizentrische Studie der Phase IIIb zur Auswertung der Immunogenität und Sicherheit des HPV-16/18-L1-AS04-Impfstoffs von GlaxoSmithKline Biologicals bei gleichzeitiger Verabreichung mit dem Kombinationsimpfstoff gegen Diphtherie, Tetanus,Keuchhusten, Kinderlähmung (Boostrix Polio) von GlaxoSmithKline Biologicals angesunde Probandinnen im Alter von 10-18 Jahren (HPV-042 GSK-108464). **EudraCT Number: 2006-003807-38**	2007	PI
Phase III	A phase II, open, randomized study in adults aged between 18 and 60 years designed to evaluate the reactogenicity and immunogenicity of a 1- and 2-dose prime-boost concept of pandemic monovalent (H5N1) influenza vaccine (split virus formulation) adjuvanted with AS03, administered according to different vaccination schedules. (H5N1-012 GSK-107495). **EudraCT Number: 2006-005477-22**	2006	PI, LKP
Phase III	A phase III, observer-blind, randomised study to evaluate the safety and immunogenicity of one and two administrations of pandemic monovalent (H5N1) influenza vaccine (split virus formulation containing 15 µg HA and adjuvanted with AS03) in adults aged 18 years and older. (GSK-107064, 107217). **EudraCT-Number 2006-001281-16**	2006	PI
Phase II	A phase II, single-blind, randomized, controlled, multicentre vaccination study to evaluate the safety and immune response of the GSK Biologicals Zoster vaccine, gE/AS01B, and to compare 3 doses of gE with AS01B adjuvant in healthy elderly subjects, aged 60 to 69 years and 70 years and above. (GSK-108494, 108516, 108518, 108520) **EudraCT-Nummer 2006-004863-69**	2006	PI, LKP
Phase III	Open study to determine the immunogenicity and reactogenicity of Influsplit SSW 2005/2006 in children from 6 years until 13 years of age. **EudraCT-Nummer 2005-004517-14**	2005	PI
Phase III	Doppelblinde, randomisierte, kontrollierte, multizentrische Studie der Phase III zur Auswertung der Sicherheit und Immunogenität des HPV-16/18-VLP/AS04-Impfstoffs von GlaxoSmithKline Biologicals bei intramuskulärer Verabreichung nach dem Schema Monat 0-1-6 an gesunde weibliche Probanden im Alter von 10-14 Jahren	2004	PI
Phase III	Offene, nach Alter stratfizierte Studie der Phase III zur Auswertung der Sicherheit und Immunogenität des HPV-16/18-VLP/AS04-Impfstoffs von GlaxoSmithKline Biologicals bei intramuskulärer Verabreichung nach dem Impfschema Monat 0-1-6 an gesunde weibliche Probanden im Alter von 15-55 Jahren. HPV-014	2004	PI

Professor Dr. med. Tino Schwarz

Klinikum Würzburg Mitte
Standort Juliusspital

List of Clinical Trials

Phase III	Doppelblinde, randomisierte, kontrollierte, multizentrische Studie der Phase III zur Auswertung der Wirksamkeit des HPV-16/18-VLP/AS04-Impfstoffs von GlaxoSmithKline Biologicals im Vergleich zum Hepatitis-A-Impfstoff als Kontrollimpfstoff zur Vorbeugung gegen persistierende zervikale Infektion durch HPV-16 oder HPV-18 oder zervikale Neoplasie bei intramuskulärer Verabreichung nach dem Schema Monat 0-1-6 bei gesunden Frauen im Alter von 15 – 25 Jahren. EudraCT-Nummer 2012-003025-25	2004	PI
Phase IV	A phase IV, uncontrolled, open-label, multi-center study in adults: Evaluation of long-term immunogenicity in subjects boosted with a new TBE vaccine for adults (free of protein-derived stabilizer) in study V48P2E1, three years after booster immunization.	2004	PI
Phase I	Randomisierte, kontrollierte, offene Phase 1-Studie zum Vergleich der Sicherheit, Verträglichkeit und Immunogenität eines Pneumokokken-Konjugatimpfstoffs in drei verschiedenen Dosierungen mit einem 23-valenten Pneumokokken-Polysaccharidimpfstoffs bei ambulant behandelten Personen ab 70 Jahre	2003	PI
Phase III	A phase III, open, randomized, multicentric study to compare the reactogenicity and immunogenicity of GlaxoSmithKline (GSK) Biologicals´ combined Vi polysaccharide typhoid vaccine and inactivated hepatitis A vaccine, HepatyrixTM, to that elicited by GSK Biologicals´hepatitis A vaccine, HavrixTM administered singly or concomitantly with GSK Biologicals`Vi polysaccharide vaccine, TypherixTM, and to that elicited by Aventis Pasteur´s monovalent Vi polysaccharid vaccine, Typhim Vi, administered intramuscularly to healthy subjects aged 18-65 years.	2002	PI
Phase III	A phase III, double-blind, controlled, multicentric randomised study, designed to evaluate the immunogenicity and reactogenicity of the combined hepatitis A / hepatitis B PFTF vaccine as compared to the combined hepatitis A 7 hepatitis B vaccine with preservative, administered according to a 3-dose schedule (0, 1, 6 months) to healthy adults aged 18 years or older)	2002	PI
Phase III	An open, randomized, multicentre, phase III clinical trial to assess the immunogenicity and reactogenicity of GSK Biologicals` dTpa-IPV vaccine compared to GSK Biologicals´ dTpa (Boostrix$^{TM}$) and IPV vaccines administered separately, and compared with Aventis Pasteur MSD`s Td-IPV vaccine (Revaxis^{R}) when administered as a single dose to health adolescents and adults. Boostrix-IPV 003	2001	PI
Phase III	A phase III, uncontrolled, open-label, multicenter study in adults: Evaluation of immunogenicity and safety of both vaccination groups that partcipated in stduy V48P2 (polygeline-free TBE vaccine, approved TBE vaccine), when boosted with polygeline-free BE vaccine 12 to 18 months after first immunization	2001	PI
Phase III	Randomisierte, kontrollierte Studie der Phase III an Erwachsenen über 18 Jahren zur Beurteilung der Konsistenz der Immunogenität von drei aufeinander folgenden Produktchargen des intradermal verabreichten Influenzaimpfstoffs mit reduziertem Thiomersalgehalt von GlaxoSmithKline Biologicals nach einem verblindeten Verfahren und zur Auswertung der Nichtunterlegenheit der Immunogenität des intradermal verabreichten Influenzaimpfstoffs mit reduziertem Thiomersalgehalt nach einem offenen Verfahren im Vergleich zu dem Fluarix^{R}-Impfstoff (in Deutschland als Influsplit SSW^{R} bekannt)	2001	PI
Phase III	Immunogenicity and safety of the iock borne encephalitis vaccine in adults: comparison of the approved vaccine (Encepur) with a new formulation containing sucrose as stabilizer instead of gelatin.	2000	PI